



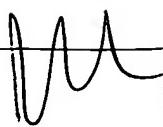
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,174	01/31/2002	Olaf Reinhold	44902-00416	9372
7590	09/09/2004		EXAMINER	
MARSH FISCHMANN & BREYFOGLE LLP 3151 SOUTH VAUGHN WAY, SUITE 411 AURORA, CO 80014			RAGONESE, ANDREA M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/062,174	REINHOLD ET AL. 
	Examiner	Art Unit
	Andrea M. Ragonese	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 June 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
 4a) Of the above claim(s) 7 and 24-36 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-6 and 8-23 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/24/02, 1/21/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election **without** traverse of **claims 1-6 and 8-23** in the reply filed on June 14, 2004 is acknowledged.
2. **Claims 7 and 24-36** are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species (Species B/C) and a nonelected invention (Group II), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 14, 2004.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. **Claim 8** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **Claim 8** recites the limitation "said airflow conduit." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. **Claims 1-4, 6, 8-10 and 21-23** are rejected under 35 U.S.C. 102(b) as being anticipated by Voges (US 5,894,841). Voges discloses a respiratory delivery system 1 comprising: at least one airflow inlet 7; at least one outlet 5; at least one airflow passage extending between the inlet 7 and the outlet 5, as shown in Figure 2; at least one ejection actuator 19 (column 6, lines 52-55); at least one airflow regulation assembly 14 (column 6, lines 17-24); wherein said respiratory delivery system 1 is selected from the group consisting essentially of oral and nasal inhalers (column 5, lines 20-25); wherein said first substance is selected from the group consisting essentially of liquid medicament and powdered medicament; wherein said at least one said ejection actuator 19 is adapted to at least assist in discharging said first substance into said airflow A (column 6, lines 52-57); wherein each said ejection actuator 19 is independently actuatable (column 5, lines 8-19); wherein said at least one airflow regulation system 14 is disposed at or near said inlet 17 of said airflow passage; wherein said at least one said airflow passage comprises a flow regulation port 15; wherein side walls of said at least one said airflow passage linearly converge in a direction of said airflow A toward said at least one said outlet 5 (claim 33); and at least one airflow monitoring assembly 16 (column 7, lines 4-46).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Voges (US 5,894,841). Voges discloses a respiratory delivery system 1 comprising all limitations recited in **claim 5**, but does not expressly disclose that the ejection actuator 19 is comprised of multiple ejection actuators. However, at the time of the invention was made, using multiple ejection actuators was known. Specifically, Voges teaches, "a typical thermal device consists of a liquid-containing chamber provided with an array of twelve coaxially divided nozzles and has twelve thin film resistors, a resistor being located directly behind each nozzle. Each nozzle supplies a droplet of liquid from the

chamber if and when the corresponding resistor is energized by a short electrical pulse. The resistors thus function as ejection means." Therefore, it would have been obvious to one having ordinary skill in the art to provide the respiratory delivery system of Voges with multiple ejection actuators as Applicant has done. Moreover, Applicant has not asserted that having more than one multiple ejection actuators provides a particular advantage, solves a stated problem or serves a purpose different from that of a respiratory delivery system with only one single ejection actuator. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with only one single ejection actuator because the substance would still be discharged into the airflow. Therefore, it would have been obvious to modify the apparatus of Vogues by modifying it to have more than one ejection actuator because it is well known in the art to utilize multiple ejection actuator in order to control the discharge of a substance from multiple nozzles in a respiratory delivery device.

11. **Claims 11-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Voges (US 5,894,841) in view of Clarke et al. (US 5,727,546). Voges discloses a respiratory delivery system 1 comprising all the limitations recited in **claims 11-20**, with the exception of a baffle for directing airflow through the use of a spring. However, the use of a baffle for directing airflow was known at the time the invention was made. Specifically, Clarke et al. teaches the use of baffle, as depicted in Figure 2(a) as "a hinged V-shaped vane 27 having two portions 23 and 24 which is able to rotate about an axis perpendicular to the pathway at hinge 25 (shown in FIGS. 2(d) and 2(e)) against the bias of spring 26" for "increasing the cross-sectional area of the pathway and

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allowing the flow of air" (column 8, lines 20-43). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus Voges by adding a spring-biased baffle because it is well known in the art, as taught by Clarke et al., use a spring-biased baffle in order to control the airflow through an inhaler.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **703-306-4055**. The examiner can normally be reached on Monday through Friday from 8 am until 4:30 pm.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR

Henry Bennett
Supervisory Patent Examiner
Group 3700